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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/917,058

07/27/2001

Martha M. Murray

18989-001 CIP
(BWH-1CIP)

2028

23628

7590

07/17/2003

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/917,058

Applicant(s)

MURRAY ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlen (WO 85/00511) in view of Bell et al. (6153292) and MacPhee et al. (6117425). Medlen discloses an implantable prosthesis for repairing a ligament defect with collagen used as a repair material and a mechanical bond using sutures is used in the method, page 14, lines 26-33. However, Medlen does not disclose using collagen I, or a protein, a neutralizing agent or a platelet in the composition. Bell et al. teach that collagen I and also a neutralizing agent (an acid) are used in connective tissue implants, col. 5, lines 29-37. Bell also teaches to include proteins in the extracellular matrix, col. 11, lines 38-45. MacPhee et al. teach that platelets are added to tissue repair implants to induce healing, col. 12, lines 13-18, col. 23, lines 32-40. It would have been obvious to one of ordinary skill in the art to substitute collagen I with a neutralizing agent and a protein as taught by Bell and also include platelets as taught by MacPhee et al. in the method of repairing a ligament tear by Medlen in order to provide a more natural implant.

Claims 19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (WO 93/21857) in view of MacPhee et al. (6117425). Li et al. disclose a prosthetic

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ligament made of collagen I, page 14, paragraph 3. Li also discloses using a neutralizing agent with the collagen, page 15, paragraph 4 – page 16, paragraph 2. Li additionally discloses that proteins can be added with the collagen material, page 20, paragraph 3. However, Li et al. do not disclose using a platelet in the collagen material. MacPhee et al. teach that platelets are added to tissue repair implants to induce healing, col. 12, lines 13-18, col. 23, lines 32-40. It would have been obvious to one of ordinary skill in the art to incorporate platelets in the collagen material as taught by MacPhee et al. in the method of repairing a ligament tear by Li et al. in order to encourage a natural healing response.

Response to Arguments

Applicant's arguments filed 5/5/03 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The fact that each of the references suggest *possible* sources of the elements in the composition that are different is irrelevant since the claims do not recite what the source of each of the elements are taken from. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some

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teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combination of references considered *as a whole* provides the motivation because the resulting composition is more like the tissue in which it is to be used for by adding the platelet, protein and neutralizing agent as taught in MacPhee and Bell respectively into the composition it provides the ability of the body of the subject to recognize it as being non-foreign. In response to the remarks that Li does not suggest contacting the ends of ruptured tissue, it must be noted that Li et al. disclose ligament repair in intra-articular joints, page 2 and that the objective of the invention was to provide a scaffold for tissue ingrowth, page 7, paragraph 2. Therefore, it is inherent that the ends of ruptured tissue are contacted with the prosthetic ligament and its composition in order to enable tissue growth to occur.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

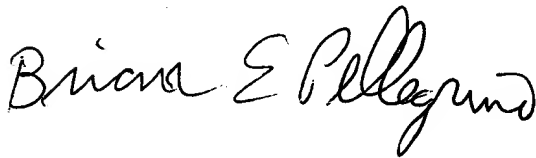
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Brian E. Pellegrino
TC 3700, AU 3738
July 16, 2003



Paul Prebilit
Primary Examiner